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UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

FAUSTO DEFRANCO,

Plaintiff,

- against -

AMENDED COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

Case No.: 14-CV-8664

STRYKER CORPORATION,

Defendant.

JURISDICTION

- 1. Plaintiff FAUSTO DEFRANCO is a resident and citizen of the State of New Jersey.
- 2. Defendant STRYKER CORPORATION is a corporation duly organized and existing under the laws of the State of Michigan, with its principal place of business in Kalamazoo, Michigan.
- 3. At all times herein mentioned, defendant was and is a foreign corporation duly authorized and licensed to conduct business in New York and was and is doing business in the State of New York.
- 4. At all times herein mentioned, defendant held itself out to the public as a foreign corporation duly authorized and licensed by the State of New York to conduct business in this State and was and is still conducting business in the State of New York.

5. The matter in controversy, exclusive of interest and costs, exceeds the sum of \$75,000.00, so that this court has jurisdiction of the subject matter of this action under 28 U.S.C. § 1332.

FIRST CLAIM FOR RELIEF (Negligence - Manufacturing)

- 6. During all of the times mentioned, defendant was engaged in the manufacture, testing, and introducing into interstate commerce for sale, a medical device, marketed under the trade name of Stryker Xia Pedicle Systems with iliac fixation ("the product") and recommended, sold, distributed, and delivered by defendant to physicians and surgeons for use and consumption by physicians and surgeons, their patients, and the general public.
- 7. Defendant knew or should have known that if the product was not properly and carefully manufactured and tested, it would cause internal damage to the person using it,
- 8. The defendant was negligent in the preparation or manufacture, in the testing, and sale of the product, more specifically, it was negligent and careless in the following respects.
- 9. October 22, 2008, plaintiff underwent surgery wherein the product was inserted into plaintiff's lumbar spine by Dr. Thomas Errico of New York University Medical Center Tish Hospital.
- 10. October 22, 2008, the product's two (2) paraspinal rods ("rods") were bilaterally placed and secured by Dr. Errico with locking caps in the pedicle screws from T2 to the sacrum.
- 11. On or about March 15, 2012, the rods of the product inserted from T2 to the sacrum failed due to metal fatigue fracture causing severe and permanent personal injuries.
 - 12. The product failed in that each rod of the product broke into two (2) parts.
 - 13. Defendant was negligent in manufacturing the product's rods that failed.

- 14. The load carrying capacities of the rods were insufficient resulting in the rods failing due to metal fatigue fracture.
- 15. Defendant was negligent in producing the rods in that the manufacturing processes, including forming, drawing, forging, extrusion, rolling, and machining, produced rough surfaces resulting in tensile residual stresses that promoted crack initiation of the rods.
- 16. April 5, 2012, NYU Medical Center, NYU Imaging's final report confirmed that there was fatigue fracture through the left sided paraspinal rod and just below the L3 pedicle screw, and fatigue fracture of the right paraspinal rod just above the L5 pedicle screw.
- 17. A Barnabas Health Saint Barnabas Medical Center, February 6, 2013 operative report documented that an operation was performed wherein the product's rods were removed from plaintiff's lumbar spine.
- 18. The operative report documented that the rods were identified spanning T12 to the pelvis bilaterally.
- 19. The operative report documented that the broken rods spanning the L3 to S5 segment were removed.
 - 20. Defendant was in other respects generally careless and negligent.
- 21. The unsafe condition of the product was known to defendant or should have been discovered by defendant in the exercise of testing the product.
- 22. Because of the defective manufacturing of the product and the failure to properly test the product, and as the result of the product being surgically inserted in plaintiff, and as a direct and proximate result of the negligence and carelessness of defendant, plaintiff suffered serious and permanent physical damage, mental and physical pain, shock and suffering, and other injuries not completely diagnosed.

- 23. That as a result of defendant's negligence, plaintiff was caused to sustain severe personal injuries which are permanent in nature.
- 24. Subsequent to the rods failing on or about March 15, 2012, plaintiff experienced a significant increase in pain.
- 25. Plaintiff's movement of his body caused the rods that had each broken into two (2) parts to scrape against each other.
- 26. The scraping of each of the rods resulting in plaintiff's body experiencing full body spasms.
- 27. Plaintiff's frequent full body spasms caused by the rods scraping against each other resulted in plaintiff losing a significant amount of his bodily strength such that plaintiff was bedridden from April 2012 until February 2013.
- 28. The failure of the rods and the resulting frequent body spasms resulted in plaintiff suffering significant depression, suicidal ideation, and ingestion of increased dosages of pain medication.
- 29. Dr. Christopher Zarro of Barnabas Health Saint Barnabas Medical Center identified the failed product as SBS-13-02335.
- 30. As a proximate result of the negligence and carelessness of defendant, plaintiff generally has been damaged in the sum of \$3,000.000.00.

SECOND CLAIM FOR RELIEF (Negligence - Design)

- 31. Plaintiff repeats, reiterates and realleges each and every allegation contained in paragraphs "1" through "30" with the same force and effect as if herein fully set forth at length.
- 32. During all of the times mentioned, defendant was engaged in the design, testing, and introducing into interstate commerce for sale, a medical device, marketed under the trade name of

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Stryker Xia Pedicle Systems with iliac fixation ("the product") and recommended, sold, distributed, and delivered by defendant to physicians and surgeons for use and consumption by physicians and surgeons, their patients, and the general public.

- 33. Defendant knew or should have known that if the product was not properly and carefully designed and tested, it would cause internal damage to the person using it,
- 34. The defendant was negligent in the preparation or design, in the testing, and sale of the product, more specifically, it was negligent and careless in the following respects.
- 35. October 22, 2008, plaintiff underwent surgery wherein the product was inserted into plaintiff's lumbar spine by Dr. Thomas Errico of New York University Medical Center Tish Hospital.
- 36. October 22, 2008, the product's two (2) paraspinal rods ("rods") were bilaterally placed and secured by Dr. Errico with locking caps in the pedicle screws from T2 to the sacrum.
- 37. On or about March 15, 2012, the rods of the product inserted from T2 to the sacrum failed due to metal fatigue fracture causing severe and permanent personal injuries.
 - 38. The product failed in that each rod of the product broke into two (2) parts.
 - 39. Defendant was negligent in designing the product's rods that failed.
- 40. The load carrying capacities of the rods were insufficient resulting in the rods failing due to metal fatigue fracture.
- 41. Defendant was negligent in producing the rods in that the product was improperly designed in that the faulty component geometry caused discontinuities such as holes, notches, and joints at the time the product was manufactured, such holes, notches, and joints, being the source of stress risers facilitating crack initiation.

- 42. The fatigue life of the notched rods was reduced resulting in each of the rods failing by breaking in two (2).
- 43. April 5, 2012, NYU Medical Center, NYU Imaging's final report confirmed that there was fatigue fracture through the left sided paraspinal rod and just below the L3 pedicle screw, and fatigue fracture of the right paraspinal rod just above the L5 pedicle screw.
- 44. A Barnabas Health Saint Barnabas Medical Center, February 6, 2013 operative report documented that an operation was performed wherein the product's rods were removed from plaintiff's lumbar spine.
- 45. The operative report documented that the rods were identified spanning T12 to the pelvis bilaterally.
- 46. The operative report documented that the broken rods spanning the L3 to S5 segment were removed.
 - 47. Defendant was in other respects generally careless and negligent.
- 48. The unsafe condition of the product was known to defendant or should have been discovered by defendant in the exercise of testing the product.
- 49. Because of the defective design of the product and the failure to properly test the product, and as the result of the product being surgically inserted in plaintiff, and as a direct and proximate result of the negligence and carelessness of defendant, plaintiff suffered serious and permanent physical damage, mental and physical pain, shock and suffering, and other injuries not completely diagnosed.
- 50. That as a result of defendant's negligence, plaintiff was caused to sustain severe personal injuries which are permanent in nature.

- 51. Subsequent to the rods failing on or about March 15, 2012, plaintiff experienced a significant increase in pain.
- 52. Plaintiff's movement of his body caused the rods that had each broken into two (2) parts to scrape against each other.
- 53. The scraping of each of the rods resulting in plaintiff's body experiencing full body spasms.
- 54. Plaintiff's frequent full body spasms caused by the rods scraping against each other resulted in plaintiff losing a significant amount of his bodily strength such that plaintiff was bedridden from April 2012 until February 2013.
- 55. The failure of the rods and the resulting frequent body spasms resulted in plaintiff suffering significant depression, suicidal ideation, and ingestion of increased dosages of pain medication.
- 56. Dr. Christopher Zarro of Barnabas Health Saint Barnabas Medical Center identified the failed product as SBS-13-02335.
- 57. As a proximate result of the negligence and carelessness of defendant, plaintiff generally has been damaged in the sum of \$3,000.000.00.

THIRD CLAIM FOR RELIEF (Strict Liability)

- 58. Plaintiff repeats, reiterates and realleges each and every allegation contained in paragraphs "1" through "57" with the same force and effect as if herein fully set forth at length.
- 59. The product described above was designed or manufactured in a defective manner by defendant, or its representatives, or by the persons from whom it obtained the product.
 - 60. The product was placed into the stream of commerce by defendant.

- 61. On or about March 15, 2012, defendant's product inserted into plaintiff in the matter in which it was to be used, plaintiff suffered severe and permanent injuries.
 - 62. These injuries were caused as a result of the product being defective.
- 63. At all of the times mentioned here, plaintiff used the product and exercised reasonable care, but due to the nature of the defects, could not discover the defects and perceive its danger.
- 64. At all of the times mentioned here, plaintiff used the product and exercised reasonable care, but due to the nature of the defects, could not avert his injuries.
- 65. At all of the times mentioned here, the product described above was in a defective condition on delivery or installation and because of the defect, was unreasonably dangerous to the public, and more specifically, to plaintiff, and because of the defect, plaintiff suffered severe and permanent injuries.
- 66. This cause of action is instituted against defendant under the doctrine of strict liability of torts.
 - 67. Plaintiff has been damaged in the sum of \$3,000,000.00.

JURY DEMAND

68. Plaintiff demands trial by jury.

PRAYER

Plaintiff requests judgment against defendant as follows:

- A. For general damages in the sum of \$3,000,000.00.
- B. For costs and disbursements;
- C. For any other relief allowed by law.

Dated: New York, New York
December 12, 2014

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Yours, etc.,

By: STEVE NEWMAN, ESQ. (8351)

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